

Information Disclosure Statements

Applicants respectfully advise the Examiner that Applicants filed a Supplemental Information Disclosure Statement on December 23, 2003 (shown on the PTO PAIR system as having a Mail Room Date of December 29, 2003). Applicants request that the Examiner initial and return a copy of the PTO-1449 that is part of that IDS.

Also, Applicants have submitted on even date herewith a Second Supplemental Information Disclosure Statement. Applicants request that the Examiner initial and return a copy of the PTO-1449 that is part of this IDS.

Rejections Pursuant to 35 U.S.C. § 102

Claims 36 – 41 and 68 – 76 stand rejected pursuant to 35 U.S.C. § 102(e) as anticipated by Lange (U.S. Patent No. 6,071,395)(hereinafter “Lange”). Applicants respectfully disagree with the rejection because Lange does not teach each and every element of independent claim 36. For example, as recited in claim 36, Lange does not teach an amplification space for amplifying nucleic acid wherein at least a part of the amplification space is identical to a part of the binding space.

Instead, Lange teaches a device where nucleic acids are bound to an adsorption medium in a reaction compartment 17 and then transferred by electrophoresis into a removal compartment 50. The separation of the reaction compartment 17 and the removal compartment 50 is best shown in FIG. 12 of Lange. FIG. 12 is described as a multiplicity of the apparatus shown in Figure 11 (see col. 5, lines 19 – 32). Figure 12 clearly shows that the reaction compartment (shown as the shaded area with orifice 80) and the removal compartment 50 are two separate compartments that are linked by a connecting channel. These two separate compartments do not show any common parts. The physical separation of the reaction compartment and the removal compartment is also explicitly shown in Figure 5.

The Examiner cites column 5, lines 46 – 67, column 6, lines 10 – 21 and column 9, lines 50 – 59 of Lange as teaching an amplification space wherein at least a part of the amplification space is identical to the binding space. However, lines 46 – 67 of column 5

teach that the eluted nucleic acids are removed from the removal compartment prior to amplification (col. 5, lines 65 – 67). Therefore, this passage from Lange does not teach that the binding space is identical to an amplification space. Similarly, nothing in column 6 teaches that at least a part of the binding space is identical to the amplification space. To the contrary, this passage teaches that the nucleic acids are transported electrophoretically from the absorption medium 100 toward the anode 20*b*. However, as shown in FIG. 11, the nucleic acids move from the absorption medium through the channel to the removal compartment 50 where anode 20(b) is located. Column 9, line 50 – 59 teach that the apparatus amplifies nucleic acids. However, this text does not provide any information regarding the physical relationship of the reaction and removal compartments. Thus, because Lange does not teach that at least part of the removal compartment is identical to the reaction compartment, Lange does not anticipate claim independent claim 36. Because Lange does not anticipate independent claim 36, Lange does not anticipate any of the claims that depend from claim 36.

Applicants note that FIGs. 8, 10, 11 and 13 are cross-sectional side views of the device of Lange. These views may have led the Examiner to conclude that there is nothing separating the reaction compartment 17 and the removal compartment 50. However, the top-view detail of FIG. 12 clearly shows that the two compartments are two separate compartments that are connected by a channel.

With regard to claims 39 – 40 and 74 – 75, the Examiner of the opinion that Lange teaches a capillary space surrounded by a heatable metal layer. The Examiner cites column 5, lines 46 – 67 and FIG. 13 of Lange as teaching a binding space and an amplification space that comprise a capillary space. Applicants respectfully disagree. There is absolutely no description of a capillary space in the cited text or in FIG 13. The Examiner refers to the “electrophoretic matrix” but fails to offer any explanation of how this comprises a capillary space. If Examiner is inclined to maintain this rejection, Applicants request that the Examiner provide some explanation of how the recited portions of Lange teach a capillary space.

For a teaching that the capillary space is surrounded by a heatable metal layer, the Examiner refers to the electrodes described in column 4, lines 52 – 67 (examiner also refers to column 9, lines 49 – 60). However, nothing in Lange teaches that the electrodes surround a capillary space and are a heatable metal layer. The electrodes are used to electrophoretically elute the nucleic acids but the electrodes do not heat the reaction vessel. By definition, the electrodes are separate elements and do not surround the reaction vessel. There is no description in Lange that there is a measurable increase in temperature when a voltage is applied to the electrodes.

Because Lange does not teach a capillary space, or a capillary space surrounded by a heatable metal layer, Lange does not anticipate claims 39 – 40 and 74 – 75.

Regarding claims 41 and 76, the Examiner cites column 5, lines 1 – 2 as teaching a polystyrene capillary space. However, this text in Lange is discussing the material of the electrodes, not a capillary space (*see* column 4, lines 65 – 67). Thus, Lange does not anticipate claims 41 and 76.

Regarding claim 68, the Examiner cites FIG 13 -- specifically “reaction compartment 17, removal compartment 50 and detection photoamplifier 314 ... surrounded by a single heatable metal layer 220” – as teaching a capillary reaction vessel coated with a single heatable metal layer. However, item 220 in FIG. 13 refers to a power supply (*see* col. 54, lines 33 – 43). The power supply does not surround any portion of the compartments 17 or 50. Thus, Lange does not anticipate claim 68.

Regarding claim 69, the Examiner refers to column 5, lines 46 – 67, column 6, lines 10 – 24, column 9, lines 28 – 66 and column 10, lines 1 – 15 as teaching a sample transport mechanism for transporting the sample and reagents through the binding space, the amplification space and the detection space. The examiner refers to the “electrophoresis device” as the transport mechanism but does not explain what specific components of the “device” comprise a transport mechanism. To the extent this device is the various compartments and the electrodes, the device does not transport sample and reagents through the compartments. The electrophoresis elements help to elute nucleic

acids but do nothing to transport sample and reagents. Thus, nothing in Lange teaches a transport mechanism. For this reason, Lange does not anticipate claim 69.

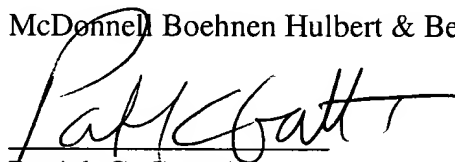
For all of the above stated reasons, Applicants respectfully submit that the rejections to the claims under 35 U.S.C. § 102(e) based upon Lange be withdrawn.

CONCLUSION

With the above amendments and remarks, Applicants respectfully submit that the application is in condition for allowance. If Examiner is of the opinion that a telephone conference would expedite prosecution of the application, Examiner is encouraged to contact Applicants' undersigned representative.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Patrick Gattari", written over a horizontal line.

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